

Our Docket No: 005493.P001



0324 0590

1655 #7

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Malcolm J. Simons

Application No.: 09/935,998

Filed: August 23, 2001

For: Intron Sequence Analysis Method
For Detection of Adjacent and
Remote Locus Alleles as Haplotypes

Examiner: Not yet assigned

Art Unit: 1655

FIRST CLASS CERTIFICATE OF MAILING

I hereby certify that I am causing the above-referenced correspondence to be deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and that this paper or fee has been addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date of Deposit: January 27, 2003

Name of Person Mailing Correspondence: Lori E. True

Lori E. True
Signature

January 27, 2003
Date

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form PTO-1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form PTO-1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ (a) within three months of the filing date of the patent application, (b) within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application, or (c) before the mailing date of a first Office Action on the merits, or (d) before the mailing date of a First Office Action after the filing of a request for continued examination under § 1.114.
- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, and includes:
- ☐ the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below).
- ☐ the fee of \$180 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), a Petition requesting consideration of the Information Disclosure Statement (see "Petition" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" below).

Copies Of The References

- ☒ Copies of certain references listed on the enclosed Form PTO-1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 C.F.R. § 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☒ Some of the references listed on the enclosed Form PTO-1449 were previously identified in the parent application of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 C.F.R. § 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 U.S.C. § 120 in which copies of the references were previously furnished are set out below:

| U.S. APPLICATIONS | | Status (<i>check one</i>) | | |
|-------------------|------------------|-----------------------------|---------|-----------|
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED | PENDING | ABANDONED |
| 1. 5,192,659 | March 9, 1993 | X | | |
| 2. 5,612,179 | March 18, 1997 | X | | |
| 3. | | | | |

Other Applications

☒ The Examiner's attention is directed to the following U.S. patent application(s):

| U.S. APPLICATIONS | | Status (<i>check one</i>) | | |
|-------------------|------------------|-----------------------------|---------|-----------|
| U.S. APPLICATIONS | U.S. FILING DATE | PATENTED | PENDING | ABANDONED |
| 10/005,626 | December 3, 2001 | | X | |
| | | | | |
| | | | | |

Certification

- ☐ The **undersigned attorney** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned attorney** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the attorney signing after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Petition

- ☐ The undersigned attorney hereby petitions the Commissioner to consider this Information Disclosure Statement and the references listed on the enclosed Form PTO-1449 in the examination of the above-identified patent application.

Fees

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.
- ☐ The **Petition Fee of \$130.00** set forth in 37 C.F.R. § 1.17(i) is enclosed herewith.

Method Of Payment Of Fees

- ☐ Attached is a check in the amount of \$ 180.00
- ☐ Charge Deposit Account No. 02-2666 in the amount of \$. (A duplicate copy of this communication is enclosed for that purpose.)

Authorization To Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 02-2666. (A duplicate copy of this communication is enclosed for that purpose.)

Instructions As To Overpayment

- ☒ Credit Account No. 02-2666.
☐ Refund

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Date: 1/27/03



Richard A. Nakashima

Reg. No.: 42,023

12400 Wilshire Blvd., 7th Floor
Los Angeles, CA 90025-1030
(303) 740-1980
(303) 740-6962 (facsimile)

Please type a plus sign (+) in this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

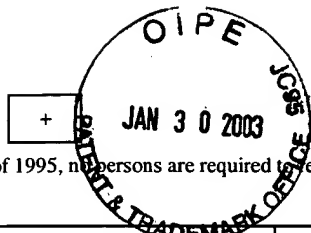
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|--|-------------|----|---|--------------------------|-------------------|
| Substitute for form 1449A/PTO (modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete if known | |
| | | | | Application Number | 09/935,998 |
| | | | | Filing Date | August 23, 2001 |
| | | | | First Named Inventor | Malcolm J. Simons |
| | | | | Group Art Unit | 1655 |
| | | | | Examiner Name | Not yet assigned |
| Attorney Docket Number | 005493.P001 | | | | |
| Sheet | 1 | of | 4 | | |

| US Patent Documents | | | | | | |
|--------------------------|----------|-----------------|----------------|-------|-----------|-------------|
| Examiner's Initials | Date | Document Number | Name | Class | Sub-Class | Filing Date |
| | 04/15/86 | 4,582,788 | Erlich | | | |
| | 07/28/87 | 4,683,194 | Saiki, et al. | | | |
| | 07/28/87 | 4,683,195 | Mullis, et al. | | | |
| | 07/28/87 | 4,683,202 | Mullis | | | |
| Foreign Patent Documents | | | | | | |
| Examiner's Initials | Date | Document Number | Country | Class | Sub-Class | Translation |
| | 10/27/87 | EPA 87309482.5 | EP | | | |
| | 06/09/87 | EPA 87305100.7 | EP | | | |
| | 10/11/89 | EPA 89310424.0 | EP | | | |
| | 02/24/88 | EPA 0256630 | EP | | | |
| | 01/06/88 | EPA 0269260 | | | | |
| | 04/18/90 | EPA 0364255 | | | | |
| | 06/21/89 | US89/02731 | PCT | | | |
| | 05/18/89 | US89/02169 | PCT | | | |
| | 11/14/88 | US88/04067 | PCT | | | |
| | 11/30/89 | WO 89/11547 | | | | |
| | 12/28/89 | WO 89/12697 | | | | |
| | 06/01/89 | WO 89/04875 | | | | |

| | | | |
|--|--|-----------------|--|
| Examiner Signature | | Date Considered | |
| <p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p> <p>¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.</p> | | | |

Please type a plus sign (+) in this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/PTO (modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete if known | |
| | | | | Applicati n Numb r | 09/935,998 |
| | | | | Filing Date | August 23, 2001 |
| | | | | First Named Inventor | Malcolm J. Simons |
| | | | | Group Art Unit | 1655 |
| | | | | Examiner Name | Not yet assigned |
| Sheet | 2 | of | 4 | Attorney Docket Number | 005493.P001 |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|----------------------|--------------------------|--|----------------|
| | | DILELLA et al., "Tight linkage between a splicing mutation and a specific DNA haplotype in phenylketonuria," <i>Nature</i> , 322, 799-803 (1986). | |
| | | DILELLA et al., "Screening for Phenylketonuria Mutations by DNA Amplification with the Polymerase Chain Reaction," <i>The Lancet</i> , pp. 497-499, (1988). | |
| | | MAEDA et al., Tissue Antigens, (1989), 34: 290-298. | |
| | | GEISEL et al., Abstract Biosis No. 87082065. | |
| | | J. Clin Chem. Clin Biochem., 26(7), 1988, 429-434. | |
| | | FUNKE et al., Biosis No. 84025060 Abstract. | |
| | | KEREM et al., Science, 245: 1073-1080 (1989). | |
| | | DENG, Nucleic Acids Research, 16(13):(6231) | |
| | | GRAHAM et al., "Application of Molecular Genetics to Prenatal Diagnosis and Carrier Detection in the Hemophilias: Some Limitations," <i>Blood</i> , 66,759-764 (1985). | |
| | | SAIKI et al., "Enzymatic Amplification of β -Globin Genomic Sequences and Restriction Site Anaylsis for Diagnosis of Sickle Cell Anemia," <i>Science</i> , 230:1350-1354 (1985). | |
| | | FUNKE et al., "Detection of a New Msp I Restriction Fragment Length Polymorphism in the Apolipoprotein A-I Gene," <i>J. Clin. Chem. Clin. Biochem.</i> , 25, 131-134 (1987). | |
| | | <i>Molecular Biology of the Gene</i> , Fourth Edition, Calif., 1987, Chapter 20: "Conserved Sequences at Exon-Intron Boundaries in Pre-mRNA," pp. 639-640. | |
| | | CLARK, "Interference of Haplotypes from PCR-amplified Samples of Diploid Populations," <i>Mol. Biol. Evol.</i> , 7(2):111-122 (1990). | |
| | | DICKER et al., "Sequence Anaylsis of a Human Gene Responsible for Drug Resistance: A Rapid Method for Manual and Automated Direct Sequencing of Products Generated by the Polymerase Chain Reaction," <i>BioTechniques</i> , 7:830-837 (1989). | |

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

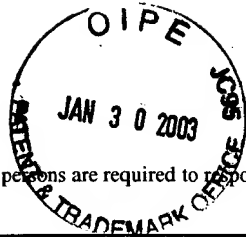
¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) in this box

+

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number



| | | | | | |
|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/PTO (modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete if known | |
| | | | | Application Number | 09/935,998 |
| | | | | Filing Date | August 23, 2001 |
| | | | | First Named Inventor | Malcolm J. Simons |
| | | | | Group Art Unit | 1655 |
| | | | | Examiner Name | Not yet assigned |
| Sheet | 3 | of | 4 | Attorney Docket Number | 005493.P001 |

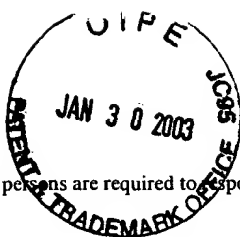
OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|----------------------|--------------------------|--|----------------|
| | | DILELLA et al., <i>The Lancet</i> , I:497-499 (1988). | |
| | | KOGAN et al., "An Improved Method for Prenatal Diagnosis of Genetic Diseases by Analysis of Amplified DNA Sequences-Application to Hemophilia A," <i>New Engl. J. Med.</i> , 317:985-990 (1987). | |
| | | MARDIS et al., "Automated Methods for Single-Stranded DNA Isolation and Dideoxynucleotide DNA Sequencing Reactions on a Robotic Workstation," <i>BioTechniques</i> , 7:840-850 (1989). | |
| | | MARX, "Disecting the Complex Diseases," <i>Science</i> , 247:1540-1542 (1990). | |
| | | RIORDAN et al., "Identification of the Cystic Fibrosis Gene Cloning and Characterization of Complementary DNA," <i>Science</i> , 245:1066-1073 (1989). | |
| | | ROMMENS et al., "Identification of the Cystic Fibrosis Gene: Chromosome Walking and Juming," <i>Science</i> , 245:1059-1065 (1989). | |
| | | SIMONS et al., pp. 952-958 In: <i>Immunology of HLA</i> , vol. 1: Springer-Verlag, New York (1989). | |
| | | STEPHENS et al., "Theoretical Underpinning of the Single-Molecule-Dilution (SMD) Method of Direct Haplotype Resolution," <i>Am. J. Hum. Genet.</i> , 46:1149-1155 (1990). | |
| | | <i>Molecular Biology of the Cell</i> , Second Edition, New York, 1989, Chapter 9: "RNA Synthesis and RNA Processing," pp. 531-535 and Chapter 10: Control of Gene Expression, pp. 602-604. | |
| | | ERLICH et al., <i>J. Forensic Sciences</i> , Sep.: 1017-1018 (1990). | |
| | | WAIKAN et al., P.N.A.S., U.S.A. vol. 75, No. 11, pp. 5631-5635, November 1978. | |
| | | ALLEN et al., <i>Biotechniques</i> , vol. 7, No. 7, pp. 736-744 (1989). | |

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) in this box



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

| | | | | | |
|--|---|----|---|--------------------------|-------------------|
| Substitute for form 1449A/PTO (modified) INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Complete if known | |
| | | | | Application Number | 09/935,998 |
| | | | | Filing Date | August 23, 2001 |
| | | | | First Named Inventor | Malcolm J. Simons |
| | | | | Group Art Unit | 1655 |
| | | | | Examiner Name | Not yet assigned |
| Sheet | 4 | of | 4 | Attorney Docket Number | 005493.P001 |

| OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|--|----------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
| | | • BOEHNKE et al., "Fine-Structure Genetic Mapping of Human Chromosomes Using the Polymerase Chain Reaction on Single Sperm: Experimental Design Considerations," <i>Am. J. Hum. Genet.</i> 45:21-32, 1989. | |
| | | • BUGAWAN, et al., "The Use of "Non-Radioactive Oligonucleotide Probes to Analyze Ezymatically Amplified DNA for Prenatal Diagnosis and Forensic HLA Typing," <i>Bio/Technology</i> , 6:943-947 (1988). | |
| | | • ERLICH et al. "HLA Typing Using DNA Probes," <i>Bio/Technology</i> , 4:975-981 (1986). | |
| | | • HYLDIG-NIELSEN et al., "Restriction Fragment Length Polymorphism of the HLA-DP Subregion and Correlations to HLA-DP Phenotypes," <i>Proc. Natl. Acad. Sci. USA</i> , 84:1644-1648 (1987). | |
| | | • JEFFREYS et al., "Amplification of Human Minisatellites by the Polymerase Chain Reaction: Towards DNA Fingerprinting of Single Cells," <i>Nucleic Acids Research</i> , 16:10953-10971, (1988). | |
| | | • NATHANS et al., "Restriction Endonucleases in the Analysis and Restructuring of DNA Molecules," <i>Annual Review of Biochemistry</i> , 44:273-293 (1975). | |
| | | • OCHMAN, et al., "Genetic Applications of an Inverse Polymerase Chain Reaction," <i>Genetics</i> , 120:621-623 (1988). | |
| | | • PADGETT et al., "Splicing of Messenger RNA Precursors," <i>Ann. Rev. Biochem.</i> , 55:1119-1150 (1986). | |
| | | • RIEß et al., "Hypervariability of intronic simple (gt)n(ga)m repeats in <i>HLA-DRB</i> genes," <i>Immunogenetics</i> , 32: 110-116 (1990). | |
| | | • RUANO et al, "Direct haplotyping of chromosomal segments from multiple heterozygotes via allele-specific PCR amplification," <i>Nucl. Acids Res.</i> 17:8392 (1989). | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.